SYNOPSIS

Rule 111-2-2
Health Planning
Certificate of Need

Rule 111-2-2-.03
Exemptions from Review

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment in totality is to modify existing regulations in light of changes in the Certificate of Need statute, O.C.G.A. § 31-6 et seq., due to the passage of Senate Bill (SB) 433 in the 2008 Georgia General Assembly. SB 433 necessitates extensive revision to the existing administrative rules for certificate of need. The revisions are outlined in detail below.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

Various grammatical and punctuation errors and omissions were corrected throughout the existing version of the regulations.

Rule 111-2-2-.03 Exemptions from Review.

This section has been renumbered to reflect additional provisions.

Rule 111-2-2-.03(4) is revised to renumber references within the rule to encompass new requirements addressed in Rule 111-2-2-.02.

Rule 111-2-2-.03(5) is revised to delete reference to Christian Science sanatoriums and replaces it with language referencing broader religious, non-medical health care institutions as defined in the United States Code.

Rule 111-2-2-.03(12) is revised to delete exemption referencing expenditures for physical plant equipment repair and replacement.

Rule 111-2-2-.03(14) is revised to replace "less" with "greater" and "85" percent with "75" percent.

Rule 111-2-2-.03(15) establishes a new exemption for a health care facility for expenditures up to $870,000 to replace/repair existing diagnostic and imaging equipment if not owned by a group practice of physicians or a hospital if such facility is in receipt of a Letter of Nonreviewability prior to July 1, 2008; does not apply to such facilities in rural counties; exempts expenditures for minor/major repairs to health care

facilities, services or equipment or replacement of equipment except as provided within the Rule.

Rule 111-2-2-.03(16) is revised to delete reference to replacement of computer or other information system, now included in another section of the Rule.

Rule 111-2-2-.03(18) establishes an exemption for expenditures for non-clinical projects.

Rule 111-2-2-.03(19) creates a new exemption for Continuing Care Retirement Communities which allows non-resident occupancy of sheltered nursing home beds on a limited basis not to exceed a 5-year period following receipt of a nursing home license and such beds are not eligible for Medicaid reimbursement.

Rule 111-2-2-.03(20) creates exemption requirements for single specialty ambulatory surgical centers that have capital expenditures up to $2.5 million; or, are the only single specialty surgery center in a county owned by the group practice and has two or fewer operating rooms; provides for assessment of penalties and/or revocation of exemption for noncompliance with exemption requirements; provides for fair notice and a hearing.

Rule 111-2-2-.03(21) creates exemption requirements for joint venture ambulatory surgery centers that have capital expenditures up to $5 million; provides for assessment of penalties and/or revocation of exemption for noncompliance with exemption requirements; provides for fair notice and a hearing.

Rule 111-2-2-.03(22) creates exemption requirements for expansion of services by an imaging center; requires department to determine if there is a need for expanded services.

Rule 111-2-2-.03(23) establishes new exemption for diagnostic cardiac catheterization in a hospital setting on patients 15 years of age or older.

Rule 111-2-2-.03(24) establishes new exemption for therapeutic cardiac catheterization in hospitals who were selected as participants in the C-PORT Study prior to July 1, 2008 and for therapeutic cardiac catheterization in hospitals who meet the criteria to participate in the C-PORT Study, as determined by the department on an annual basis, but who have not been selected for participation.

Rule 111-2-2-.03(25) establishes new exemption for infirmaries or facilities operated by, or on behalf of, or under contract with the Department of Corrections or the Department of Juvenile Justice.

Rule 111-2-2-.03(26) establishes new exemption for skilled nursing or intermediate care facility to relocate within the same county, any other health care facility in a rural county to relocate within the same county and any other health care facility in an urban county to relocate within a three-mile radius of the existing facility as long as no new or expanded services will be offered at the new location.

Rule 111-2-2-.03(27) creates exemption for facilities that provide treatment for persons who have traumatic brain injury.

Clarifying language is added to the Rule to provide that persons with a valid exemption prior to July 1, 2008, will not be required to obtain a certificate of need to continue to offer the previously offered services.

111-2-2-.03 Exemptions from Review.

The following shall not be subject to Certificate of Need review and shall be exempted from the provisions of these Rules regarding Certificate of Need Review except as otherwise provided:

(1) infirmaries operated by educational institutions for the sole and exclusive benefit of students, faculty members, officers, or employees thereof;

(2) infirmaries or facilities operated by businesses for the sole and exclusive benefit of officers or employees thereof, provided that such infirmaries or facilities make no provision for overnight stay by persons receiving their services;

(3) institutions operated exclusively by the federal government or by any of its agencies;

(4) offices of private physicians or dentists, as determined in the sole discretion of the Department, whether for individual or group practice except as otherwise provided in 111-2-2-.01(~~33~~ 49)~~(h)~~ and 111-2-2-.01(~~33~~ 39)(f)~~(i)~~. Simple ownership of a facility by a practitioner or a group of practitioners of the healing arts does not, in and of itself, exempt such facility from the scope of these Rules. Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied exclusively as the office of private physicians or dentists. Therefore, any person who seeks licensure as a health care facility must secure a certificate of need if a new institutional health service is being offered or developed;

(5) ~~Christian Science sanatoriums operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts~~ Religious, nonmedical health care institutions as defined in 42 U.S.C. § 1395x(ss)(1), listed and certified by a national accrediting organization ;

(6) site acquisitions for health care facilities or preparation or development costs for such sites prior to filing a Certificate of Need application;

(7) expenditures related to adequate preparation and development of an application for a Certificate of Need;

(8) the commitment of funds conditioned upon the obtaining of a Certificate of Need;

(9) transfers from one health care facility to another such facility of major medical equipment previously approved under or exempted from Certificate of Need review, except where such transfer results in the institution of a new clinical health service for which a Certificate of Need is required in the facility acquiring said equipment, provided that such transfers are recorded at net book value of the medical equipment as recorded on the books of the transferring facility;

(10) expenditures for the acquisition of existing health care facilities by stock or asset purchase, merger, consolidation, or other lawful means, unless the facilities are owned or operated by or on behalf of a:

(a) Political subdivision of this state;

(b) Combination of such political subdivision; or

(c) Hospital authority, as defined in Article 4 of Chapter 7 of Title 31.

(11) expenditures for the restructuring of or for the acquisition by stock or asset purchase, merger, consolidation, or other lawful means of an existing health care facility which is owned or operated by or on behalf of any entity described in 111-2-2-.03(10) only if such restructuring or acquisition is made by any entity described in 111-2-2-.03(10);

~~(12) expenditures for the repair or replacement of equipment associated with the physical plant, provided the expenditures do not exceed the threshold for capital expenditures;~~

(~~13~~ 12) capital expenditures otherwise covered by this Chapter required solely to eliminate or prevent safety hazards as defined by federal, state or local fire, building, environmental occupational health, or life safety codes of regulations, to comply with licensing requirements of the Department of Human Resources, or to comply with accreditation standards of the Joint Commission on Accreditation of Health Care Organizations;

(~~14~~ 13) except as otherwise provided in this subsection, all cost overruns are excluded from prior Certificate of Need review and approval. For purposes of this subsection, a cost overrun that is subject to prior Certificate of Need review and approval (i.e., a reviewable cost overrun) is defined as meaning any cost overrun which is in excess of the current capital or diagnostic or therapeutic equipment threshold, or in excess of 10 percent of the approved capital expenditure amount, whichever is less. However, in no event shall an additional expenditure of less than $300,000 be deemed a reviewable cost overrun. Reviewable cost overruns will be reviewed by the Department in accordance with the following provisions:

(a) A reviewable cost overrun associated with ongoing construction or renovation activity which has not been incurred prior to a Certificate of Need approval and is solely related to an unanticipated engineering, major fixed equipment or other construction problem, or federal, state or local fire requirements which were adopted or became effective after the issuance of the Certificate of Need but prior to the completion of construction or renovation, will receive favorable review consideration if the applicant demonstrates that the overrun will have no impact or a minimal impact on costs and/or charges per patient day or procedure; and

(b) A reviewable cost overrun which is the result of subsequent project bidding prior to any contractual obligation for construction and/or renovation work will not receive favorable review consideration by the Department but will require the entire project to be reviewed as an entirely new project subject to all the applicable criteria, standards and plans; and

(c) A reviewable cost overrun which is due to delays of project construction and/or renovation activity resulting from an appeal proceeding, when such delay has been in excess of one year, and where the Department has suspended the time periods until the issues are resolved, will be given favorable consideration as long as the project has not changed in scope, square footage, services or number of new beds proposed.

(d) For projects involving either construction or renovation, but not both, a reviewable cost overrun which increases the square footage beyond 5 percent of the originally approved project's total new square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(e) For projects involving construction and renovation, a reviewable cost overrun which increases the square footage beyond 5 percent of the sum of the new construction square footage and renovated square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(f) Regardless of cost, during implementation of the project, any increase in the scope of the original project or any change in the number of beds (i.e., the subtraction, addition, replacement or conversion of different number of beds than authorized in the original Certificate of Need) will invalidate the original project and the Department will deem the original project to have been withdrawn unless prior written approval is obtained from the Department.

(15 14) increases in the bed capacity of a hospital up to ten beds or ten percent of capacity, whichever is ~~less~~ greater, in any consecutive two-year period, in a hospital that has maintained an overall occupancy rate greater than ~~85~~ 75 percent (exclusive of any skilled nursing units or comprehensive inpatient rehabilitation units) for the previous 12 month period;

(~~16~~ 15) expenditures of less than $870,000.00 for any minor or major repair or replacement of equipment by a health care facility that is not owned by a group practice of physicians or a hospital and that provides diagnostic imaging services if such facility received a letter of nonreviewability from the department prior to July 1, 2008. This paragraph shall not apply to such facilities in rural counties. ~~for the replacement of diagnostic or therapeutic equipment, including, but not limited to, CT scanners.~~

(15.1) except as provided in paragraph (15) of this subsection, expenditures for the minor or major repair of a health care facility or a facility that is exempt from the requirements of these rules, parts therof or services provided or equipment used therein; or the replacement of equipment, including but not limited to CT scanners previously approved for a certificate of need.

(a) To qualify for this exemption, the replaced equipment must have received prior CON review and approval, or have been grandfathered, and the replaced equipment must be removed entirely from the premises and not be used in tandem with the replacement equipment, unless authorized in writing by the Department. Replacement equipment must be placed in the same defined location as the replaced equipment.

1. The Department may authorize in writing the retention of certain functionality of the equipment to be replaced if such retained functionality is not used in tandem with the replacement equipment and if the retained functionality would not otherwise result in the provision of a new institutional health service. The fair market value of the retained functionality must not exceed the applicable equipment threshold at the time of replacement.

(b) Expenditures associated with activities essential to acquiring and making operational the replacement equipment shall also be exempted from review. "Activities essential to acquiring and making operational the replacement equipment" means those activities that are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

(c) Replacement equipment shall be comparable diagnostic or therapeutic equipment in relation to the replaced equipment. "Comparable diagnostic or therapeutic equipment" means equipment which is functionally similar and which is used for the same or similar diagnostic or treatment purposes. Replacement equipment is comparable to the equipment being replaced if it is functionally similar and is used for the same or similar diagnostic, therapeutic, or treatment purposes as the equipment currently in use and is not used to provide a new health service;

(~~17~~ 16) new institutional health services offered by or on behalf of a Health Maintenance Organization, or a health facility controlled, directly or indirectly, by a Health Maintenance Organization or a combination of Health Maintenance Organizations, provided specific and detailed documentation is provided to the Department that one of the following conditions are met:

(a) that 75 percent of the patients who can reasonably be expected to use the service will be individuals enrolled in a Health Maintenance Organization certified by the State of Georgia;

(b) that the service is needed by the Health Maintenance Organization in order to operate efficiently and economically and that it is not otherwise readily accessible to the Health Maintenance Organization because:

1. existing similar services are not available under a contract of reasonable duration;

2. full and equal staff privileges are not available in existing facilities; or

3. arrangements with existing facilities are not administratively feasible;

~~(18) the addition to or replacement of computer or other information systems; and~~

(~~19~~ 17) capital expenditures for a project otherwise requiring a Certificate of Need if those expenditures are for a project to remodel, renovate, replace, or any combination thereof, a medical-surgical hospital and all the following conditions are met:

(a) the hospital has a bed capacity of not more than 50 beds;

(b) the hospital is located in a county in which no other medical-surgical hospital is located;

(c) the hospital has at any time been designated as a disproportionate share hospital by the Department;

(d) the hospital has at least 45 percent of its patient revenues derived from Medicare, Medicaid, or any combination thereof, for the immediately preceding three years;

(e) the project has at least 80 percent of its capital expenditures financed by proceeds of a special purpose county sales and use tax imposed pursuant to Article 3 of Chapter 8 of Title 48;

(f) the proposed replacement hospital is located within a three-mile radius of and within the same county as the hospital's existing facility; and

(g) the project does not result in any of the following:

1. the offering of any new clinical health services;

2. any increase in bed capacity;

3. any redistribution of existing beds among existing clinical health services; and

4. any increase in the capacity of existing clinical health services.

(18) Expenditures for nonclinical projects, including parking lots, parking decks, and other parking facilities; computer systems, software, and other information technology; medical office buildings; and state mental health facilities;

(19) Continuing care retirement communities, provided that the skilled nursing component of the facility is for the exclusive use of residents of the continuing care retirement community and that a written exemption is obtained from the Department; provided, however, that new sheltered nursing home beds may be used on a limited basis by persons who are not residents of the continuing care retirement community for a period up to five years after the date of issuance of the initial nursing home license, but such beds shall not be eligible for Medicaid reimbursement. For the first year, the continuing care retirement community sheltered nursing facility may utilize not more than 50 percent of its licensed beds for patients who are not residents of the continuing care retirement community. In the second year of operation, the continuing care retirement community shall allow not more than 40 percent of its licensed beds for new patients who are not residents of the continuing care retirement community. In the third year of operation, the continuing care retirement community shall allow not more than 30 percent of its licensed beds for new patients who are not residents of the continuing care retirement community. In the fourth year of operation, the continuing care retirement community shall allow not more than 20 percent of its licensed beds for new patients who are not residents of the continuing care retirement community. In the fifth year of operation, the continuing care retirement community shall allow not more than 10 percent of its licensed beds for new patients who are not residents of the continuing care retirement community. At no time during the first five years shall the continuing care retirement community sheltered nursing facility occupy more than 50 percent of its licensed beds with patients who are not residents under contract with the continuing care retirement community. At the end of the five-year period, the continuing care retirement community sheltered nursing facility shall be utilized exclusively by residents of the continuing care retirement community and at no time shall a resident of a continuing care retirement community be denied access to the sheltered nursing facility. At no time shall any existing patient be forced to leave the continuing care retirement community to comply with this paragraph. The Department is authorized to promulgate rules and regulations regarding the use and definition of 'sheltered nursing facility' in a manner consistent with this Code section. Agreements to provide continuing care include

agreements to provide care for any duration, including agreements that are terminable by either party;

(20) Any single specialty ambulatory surgical center that:

(a) 1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health services which do not exceed $2,500,000.00; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two or fewer operating rooms; provided, however, that a center exempt pursuant to this paragraph shall be required to obtain a certificated of need in order to add any additional operating rooms;

(b) Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. Hospitals shall not unreasonably deny a transfer agreement or affiliation agreement to the center;

(c) 1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than 2 percent of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids™ Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ benficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than 4 percent of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

(d) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70.

Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.' The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed

project for purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with an simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop certificate of need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(21) Any joint venture ambulatory surgical center that:

(a) Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5,000,000.00;

(b) 1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids™ beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than 2 percent of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids™ Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids ™ beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than 4 percent of its adjusted gross revenue; and

(c) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70.

Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.' The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed project for purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop certificate of need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(22) Expansion of services by an imaging center based on a population needs methodology taking into consideration whether the population residing in the area served by the imaging center has a need for expanded services, as determined by the Department in accordance with its rules and regulations, if such imaging center:

(a) Was in existence and operational in this state on January 1, 2008;

(b) Is owned by a hospital or by a physician or a group of physicians comprising at least 80 percent ownership who are currently board certified in radiology;

(c) Provides three or more diagnostic and other imaging services;

(d) Accepts all patients regardless of ability to pay; and

(e) Provides uncompensated indigent and charity care in an amount equal to or greater than the amount of such care provided by the geographically closest general acute care hospital; provided, however, this paragraph shall not apply to an imaging center in a rural county;

(23) Diagnostic cardiac catheterization in a hospital setting on patients 15 years of age and older;

(24) Therapeutic cardiac catheterization in hospitals selected by the Department prior to July 1, 2008, to participate in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Study and therapeutic cardiac catheterization in hospitals that, as determined by the Department on an annual basis, meet the criteria to participate in the C-PORT Study but have not been selected for participation; provided, however, that if the criteria requires a transfer agreement to another hospital, no hospital shall unreasonably deny a transfer agreement to another hospital;

(25) Infirmaries of facilities operated by, on behalf of, or under contract with the Department of Corrections or the Department of Juvenile Justice for the sole and exclusive purpose of providing health care services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution, including correctional institutions operated by private entities in this state which house inmates under the Department of Corrections or the Department of Juvenile Justice;

(26) The relocation of any skilled nursing facility or intermediate care facility within the same county, any other health care facility in a rural county within the same county, and any other health care facility in an urban county within a three-mile radius of the existing facility so long as the facility does not propose to offer any new or expanded clinical health services at the new location;

(27) Facilities which are devoted to the provision of treatment and rehabilitative care for periods continuing for 24 hours or longer for persons who have traumatic brain injury, as defined in O.C.G.A. § 37-3-1.

Pursuant to O.C.G.A. § 31-6-40(c)(1), any person who had a valid exemption granted or approved by the former Health Planning Agency or the Department of Community Health prior to July 1, 2008, shall not be required to obtain a certificate of need in order to continue to offer those previously offered services.

Authority O.C.G.A. §§ 31-5A et seq. and 31-6 et seq.